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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/650,038      | 08/28/2003  | Michael Haisch       | 0902-005            | 6948             |

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POTOMAC PATENT GROUP, PLLC  
P. O. BOX 270  
FREDERICKSBURG, VA 22404

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| EXAMINER |
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LAVARIAS, ARNEL C

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

2872

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/650,038

Applicant(s)

HAISCH ET AL.

Examiner

Arnel C. Lavarias

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 6/28/06, 3/23/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-11, 30-32, 35 and 40-52 is/are pending in the application.
- 4a) Of the above claim(s) 41, 42 and 44-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-11, 30-32, 35, 40 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/23/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Drawings***

1. The replacement drawings were received on 3/23/06. These drawings are acceptable.

### ***Response to Amendment***

2. The amendments to the specification of the disclosure in the submission dated 6/28/06 are acknowledged and accepted.
3. The amendments to the abstract of the disclosure in the submission dated 3/23/06 are acknowledged and accepted. In view of these amendments, the objections to the abstract in Section 12 of the Office Action dated 9/23/05 are respectfully withdrawn.
4. The amendments to Claims 8-10, 30-32, 35, 40, 51 in the submission dated 6/28/06 are acknowledged and accepted. In view of these amendments, the objections to the claims in Section 14 of the Office Action dated 9/23/05 are respectfully withdrawn.

### ***Response to Arguments***

5. The Applicants argue that, with respect to newly amended Claim 8, as well as Claims 9-11, 30-32, 43 which depend to Claim 8, Kitajima fails to teach or reasonably suggest first image data representing plural images of the object region sequentially detected, and a display system configured to sequentially display plural second representations. After reviewing Kitajima, the Examiner agrees, and respectfully withdraws the rejections of Claims 8-11, 30-32, 43 in Sections 16, 19-21 of the Office Action dated 9/23/05.

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6. The Applicants further argue that, with respect to newly amended Claim 35, Kitajima fails to teach or reasonably suggest displaying the recorded series of plural fluorescent light images of the object. After reviewing Kitajima, the Examiner agrees, and respectfully withdraws the rejections of Claim 35 in Section 16 of the Office Action dated 9/23/05.

7. The Applicants argue that, with respect to newly amended Claim 40, the subject matter disclosed in Claim 40 is entirely attributable to inventor Andreas Raabe, and thus the Raabe et al. article does not qualify as a 102(a) reference. The Examiner respectfully disagrees. The instant application has been issued a requirement for restriction (See Office Actions dated 5/26/05, 1/25/05), to which Applicants have made an election (See response filed 2/25/05, 7/26/05) as well as a request for change in inventorship (See submission filed 7/26/05), which was accepted (See Section 5 of the Office Action dated 9/23/05). As previously set forth in Section 2 of the Office Action dated 9/23/05, the inventive entity for the instant application (which currently includes pending Claims 8-11, 30-32, 35, 40-52) is currently Michael Haisch, Christoph Hauger, Gerhard Gaida, and Andreas Raabe. However, the inventive entity attributed to the subject matter disclosed on Page 133 in the paragraph under the heading "Technique for ICG Video Angiography" (See the article, A. Raabe et al., "Near-Infrared Indocyanine Green Video Angiography: A New Method for Intraoperative Assessment of Vascular Flow", Neuro Surgery, vol. 52, no. 1, January 2003, pp. 132-139.) is Andreas Raabe, which is different than the inventive entity of the instant application. 35 U.S.C. 102(a) states that "A person shall be entitled to a patent unless the invention was known or used *by others* in this

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country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.” Since the inventive entity of the instant application (including Claim 40) and the inventive entity attributed to the subject matter disclosed on Page 133 of Raabe et al. are different, the rejection of Claim 40 in Section 17 of the Office Action dated 9/23/05 appears to be proper.

8. The Applicants finally argue that, with respect to newly amended Claim 40, Chari et al. and Ohishi et al. fail to teach or reasonably suggest assessing a complete blocking of the aneurysm sac with the clip based on the at least one fluorescence image. The Examiner respectfully disagrees. Both Chari et al. and Ohishi et al. disclose the assessment of the aneurysm therapies applied (e.g. compound introduction, aneurysm clipping, coil introduction) wherein the assessment includes taking fluorescence images of the blood flow before and after the aneurysm therapy, and evaluating the therapy based on these images (See Figure 1, Page 7, lines 5-27 of Chari et al.; See Figures 1, 3-4, col. 4, line 19-col. 9, line 10, and especially col. 7, lines 29-col. 8, line 6 of Ohishi et al.), i.e. an assessment may be made to determine how well the aneurysm therapy succeeded based on the amount of fluorescent indicator that flows into the aneurysm.

9. Claims 8-11, 30-32, 35, 40, 43 are rejected as follows.

### *Specification*

10. The disclosure is objected to because of the following informalities:

Page 20, line 27- ‘84’ should read ‘85’.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claim 40 is rejected under 35 U.S.C. 102(a) as being anticipated by Raabe et al. (A. Raabe, J. Beck, R. Gerlach, M. Zimmermann, V. Seifert, “Near-Infrared Indocyanine Green Video Angiography: A New Method for Intraoperative Assessment of Vascular Flow”, Neuro Surgery, vol. 52, no. 1, January 2003, pp. 132-139.), of record.

Raabe et al. discloses a method of treating an aneurysm of a patient (See in particular Pages 133-134; Table 1), the method comprising clipping an aneurysm sac of the aneurysm using a clip; injecting indocyanine green into the patient; generating at least one fluorescence image of at least one artery adjacent to the clipped aneurysm; assessing vascular blood flow of the at least one artery based on the at least one fluorescence image; and assessing a complete blocking of the aneurysm sac with the clip based on the at least one fluorescence image (See specifically ‘Case 3 (Patient 12)’ on Page 134, which discloses the assessment of the complete blocking, or lack thereof due to residual filling).

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 8, 30-31, 35, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima (U.S. Patent No. 5865829), of record, in view of Frangioni (U.S. Patent Application Publication US 2005/0182321 A1).

Kitajima discloses a microscopy system for visualizing a fluorescence of a fluorescent substance in an object to be inspected (See for example Figures 1-4, 7-8, 10), wherein the microscopy system comprises a microscopy optics having a first beam path (See light paths passing from element 13 to elements 91, 91' via 80, 80', then to 90 in Figure 8; col. 8, line 53-col. 14, line 67) for optically imaging an object region onto a light detecting component of a first camera (See 91, 91' in Figure 8) for generating first image data representing images of the object region with light including wavelengths of a first wavelength range comprising a fluorescent emission wavelength of the fluorescent substance, and a second beam path (See light paths passing from element 13 to element 2 via 80, 80' and 35, 45 in Figure 8; col. 8, line 53-col. 14, line 67) for providing a magnified first representation of the object region, wherein the first representation represents images of the object regions with light including wavelengths of a second wavelength range comprising at least visible light; an image memory (See 160, 161 in Figure 8) for storing a set of first image data representing at least one image of the object

region detected by the first camera during at least a time duration; and a display system (See 93, 93' in Figure 8) configured to display at least one second representations generated from at least a subset of first image data such that the at least one second representations is displayed in superposition with the first representation for observation by a user (See also Figure 12). Kitajima additionally discloses the second beam path comprising at least one ocular for representing the magnified first representation of the object region (See 35, 45 in Figure 8); the display system being further configured to superimpose the at least one second representation with the second beam path directed to the ocular (See Figure 8; col. 53-col. 14, line 67); and the fluorescent substance comprises indocyanine green (See col. 12, lines 1-2). Kitajima additionally discloses a microscopy method (See Figures 8, 12; col. 8, line 53-col. 14, line 67) for visualizing a fluorescence of an object to be inspected, the method comprising displaying a magnified first representation of the object for observation by a user, wherein the fluorescence of the object is substantially not visible in the first representation; recording a series of fluorescence light images of the object during a time duration; and displaying the recorded series of fluorescent light images of the object after the time period has lapsed (it is noted that there is an inherent time delay between recording the images on the camera and displaying these images on the display system) such that the series of fluorescent light images is visible for the user and superimposed with the magnified first representation of the object. Kitajima does not explicitly disclose the images being plural images and the display system sequentially displaying plural second representations. However, generating plural sequential images and displaying such images is well known



in the art. For example, Frangioni teaches a conventional medical imaging optical system (See for example Figures 1, 3-4) which provides simultaneous rendering of visible and fluorescent light images (See Abstract; Figure 4). In particular, Frangioni teaches the use of cameras both for the infrared light and visible light detection (See Paragraphs 0103-0107), which generate superimposed sequential images at a rate of approximately 15 frames a second and is displayed by a display (See 126 in Figure 1; 326 in Figure 3). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the images be plural images and the display system sequentially display plural second representations, as taught by Frangioni, in the system and method of Kitajima, for the purpose of providing a near-real-time (as opposed to a static) display of the image field.

15. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima in view of Frangioni.

Kitajima discloses the invention as set forth above in Claim 8, but does not explicitly disclose the display system being configured for repeatedly displaying the series of plural second representations in superposition with the first representation. However, since Kitajima discloses that the series of image data are specifically stored in image memory (See 160, 161 in Figure 8) controllable via controller 66, it would have been readily evident and obvious to one having ordinary skill in the art to play back the stored image data in the image memory one or more times, as well as perform any number of other image processing functions on the image data stored in the image memory. One would

have done this to simplify reviewing series of complex images without having to memorize or recall from one's memory, thus reducing mistakes.

16. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima in view of Frangioni as applied to Claim 8 above, and further in view of Furusawa et al. (U.S. Patent No. 6371908), of record.

Kitajima in view of Frangioni discloses the invention as set forth above in Claim 8, except for the controller configured to select the subset of the set of first image data from the set of first image data based on intensities of the plural images represented by the first image data. However, Furusawa et al. teaches a conventional color observation system for use in an optical imaging system (See Figures 1-4), such as an endoscope, wherein fluorescence image data recorded from the CCD camera (See 17 in Figure 1) is sent to a video processor (See 13 in Figure 1). The video processor is configured to select a subset from the image data based on differences in intensities (particularly with respect to a baseline level) of the images in the image data (See Figures 5-14; col. 7, line 32-col. 11, line 59), and display a composite visible/fluorescence image. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the controller of Kitajima in view of Frangioni, be configured to select the subset of the set of first image data from the set of first image data based on intensities of the plural images represented by the first image data, as taught by Furusawa et al., to simplify detection and identification of abnormal conditions of the observation object in the composite images.

17. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima in view of Frangioni as applied to Claim 8 above, and further in view of Imaizumi et al. (JP 10325798A), of record.

Kitajima in view of Frangioni discloses the invention as set forth above in Claim 8, except for the first beam path comprising at least one light detecting component of a second camera for generating second image data representing images of the object region with visible light. However, Imaizumi et al. discloses a conventional microscope apparatus (See for example Figure 1), including a first beam path (See light paths passing from element 2 to element 63, then to 70, 72, 71 in Figure 1) for optically imaging an object region onto a light detecting component of a first camera (See 71 in Figure 1) for generating first image data representing images of the object region with light including wavelengths of a first wavelength range comprising a fluorescent emission wavelength of the fluorescent substance, and a second beam path (See light paths passing from element 2 to element 64 in Figure 1) for providing a magnified first representation of the object region, wherein the first representation represents images of the object regions with light including wavelengths of a second wavelength range comprising at least visible light. In addition, the first beam path also includes a light detecting component of a second camera for generating second image data representing images of the object region with visible light (See 72 in Figure 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the first path of the microscope system of Kitajima in view of Frangioni, further include at least one light detecting component of a second camera for generating second image data representing

images of the object region with visible light, as taught by Imaizumi et al., for the purpose of providing simultaneous observation and storage of both fluorescence and visible light image data, both of which may be played back at a later time.

18. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chari et al. (WO01/22870A1) in view of Ohishi et al. (U.S. Patent No. 6721590).

Chari et al. discloses a method of treating an aneurysm of a patient (See Figure 1; Page 5, line 31-Page 6, line 4; Page 7, lines 5-27; Page 8, line 28-Page 11, line 10), the method comprising administering a therapy to an aneurysm; injecting indocyanine green into the patient; generating at least one fluorescence image of at least one artery adjacent to the aneurysm under study (It is noted that the injection and generation steps may be performed before, as well as after, the administration of the therapy to the aneurysm, See Page 7, lines 5-27); assessing vascular blood flow of the at least one artery based on the at least one fluorescence image; and assessing a complete blocking of the aneurysm based on the at least one fluorescence image (See Figure 1, Page 7, lines 5-27). Chari et al. does not explicitly disclose the specific step of administering a therapy to an aneurism including clipping an aneurysm sac of the aneurysm using a clip. However, Ohishi et al. teaches various therapeutic methods of aneurysms, including clipping and insertion of a coil-like occluding material into the aneurysm (See col. 1, line 6-28). These therapeutic methods may be done in conjunction with fluorescence imaging techniques (See Figures 1, 3-4), so as to assess the blood flow, or lack thereof, to the aneurysm (See Figures 1, 3-4; col. 4, line 19-col. 9, line 10, and especially col. 7, lines 29-col. 8, line 6). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention

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was made to have the step of administering a therapy to an aneurysm, as disclosed by Chari et al., include clipping an aneurysm sac of the aneurysm using a clip, as taught by Ohishi et al., for the purpose of preventing blood from flowing into the aneurysm, which may burst due to increased blood pressure and cause injury or death.

***Conclusion***

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arnel C. Lavarias whose telephone number is 571-272-2315. The examiner can normally be reached on M-F 9:30 AM - 6 PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Drew Dunn can be reached on 571-272-2312. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Arnel C. Lavarias  
Primary Examiner  
Group Art Unit 2872  
8/18/06

## REPLACEMENT SHEET

4/5

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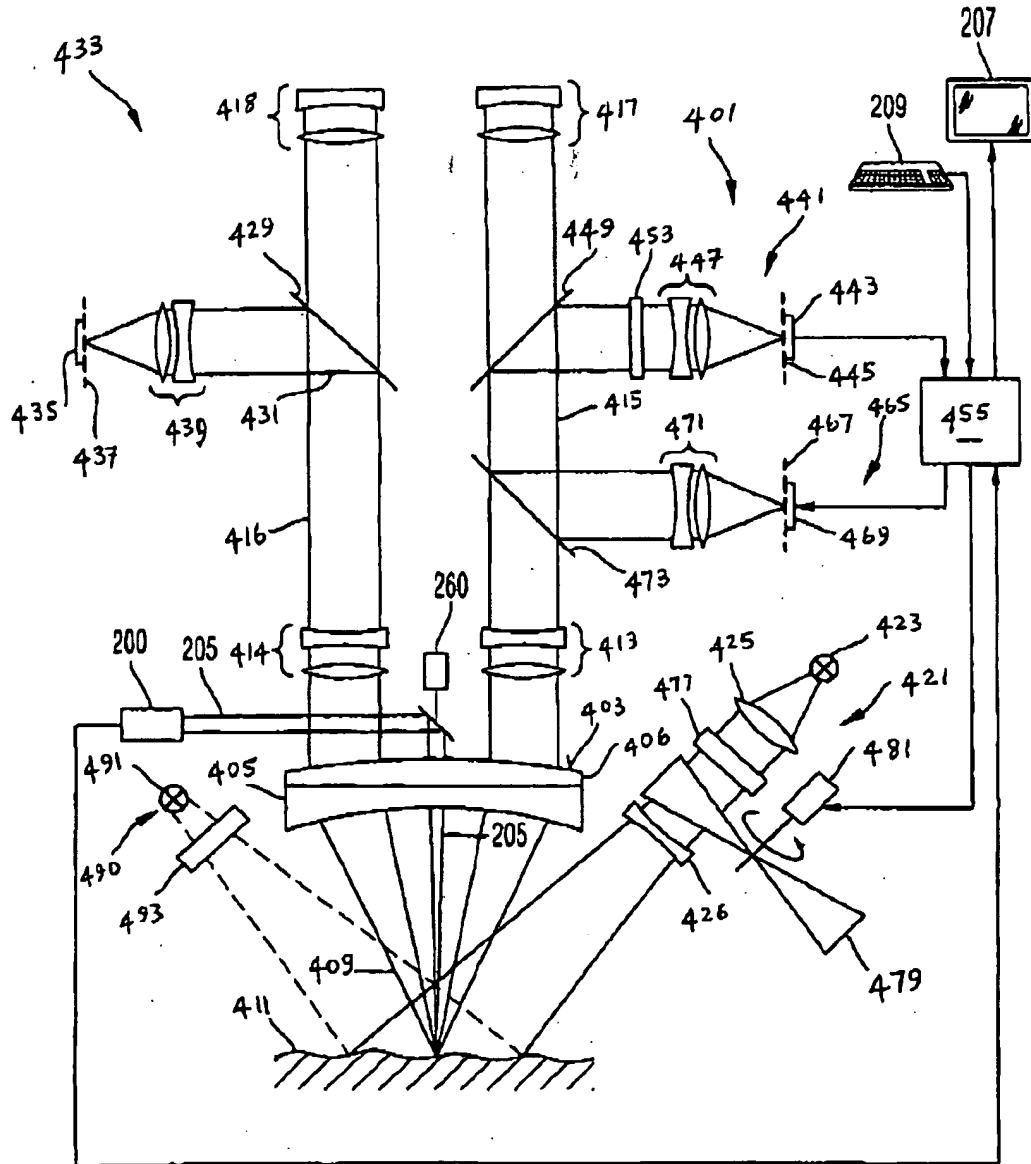


Fig. 4

REPLACEMENT SHEET

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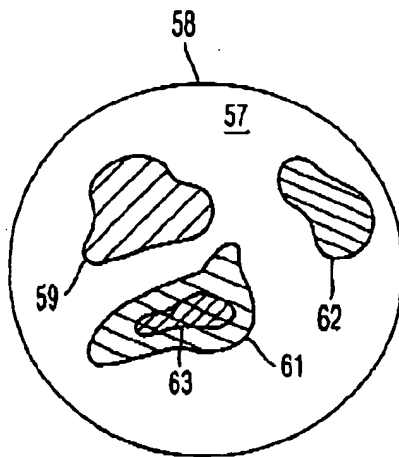


Fig. 5a

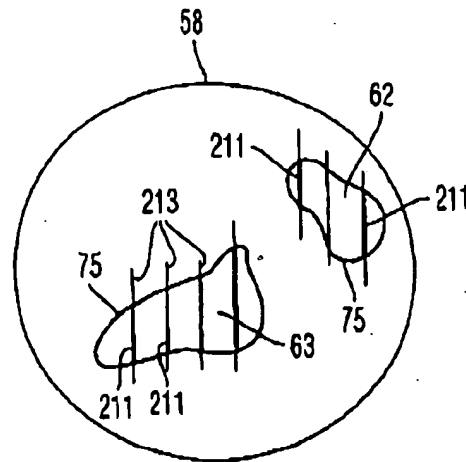


Fig. 5b

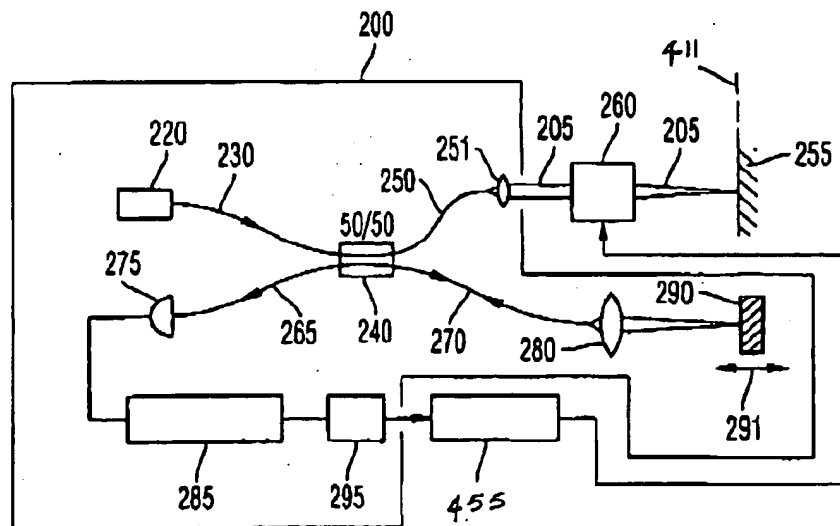


Fig. 6